

REMARKS

Status of the Claims

Claims 1-24 are pending in the present application. Claims 1, 5-9, 17, 20 and 21 are amended in the present communication. Claims 25-48 are withdrawn from consideration. The withdrawn claims all ultimately depend from independent Claim 1. Consequently, Applicants respectfully request rejoinder of the withdrawn claims in the event that Claim 1 is found allowable.

Amendments to the Claims

Claim 1 is amended to clarify that the device comprises a “single” support and that the composition is retained “within the support.” Claims 5-9 are amended to emphasize that “the composition is retained inside the recess or space of each sample zone.” Support for these amendments can be found throughout of the specification, more particularly in Figs. 1 and 2.

Claim 17 is amended to correct a spelling error.

Claim 20 is amended to replace the phrase “such as for example” with the word “including” in response to the rejection under 35 USC §112, second paragraph for indefiniteness.

Claim 21 is amended to depend from Claim 11.

Claim Rejections

35 USC §112

Claim 20 is rejected under 35 USC §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 20 is amended to replace the phrase “such as for example” with the word “including.” Applicants respectfully request reconsideration and withdrawal of the rejection in view of the foregoing amendment to claim 20.

35 USC §102***Yokoyama et al.***

Paragraph 8 of the Office Action states that Claims 1-5, 9-13, 16, 17, 22 and 23 are rejected under 35 USC §102(b) as being anticipated by Yokoyama et al. (US 2004/0147854 A1). However, Paragraph 12 states that “Yokohama meets the limitations of claims 1-6, 9-16, 22 and 23.” Moreover, paragraphs 9-11 of the Office Action provide rationales for the rejection of claims 1-6, 9-14, 16, 22 and 23, but not claims 7, 8, 15, 17-21 and 24. Applicants respectfully traverse the rejection as the Yokoyama fails to teach all the limitations of claims 1-6, 9-17, 22 and 23.

Yokoyama et al. describe an instrument for collecting and sampling oral secretata, which simultaneously sterilizes oral bacteria and suppresses the decomposition of D-glucose in the oral secretata liquid. The Yokoyama et al. reference does not teach “a device for collecting and preserving nucleic acids in a sample” as set forth in independent Claim 1, “where the one or more than one sample zone on the support comprises a recess or space within the support” and “where a composition comprising i) one or more than one absorbent, and ii) one or more than one stabilizer in a solid state”... “is retained within the support inside the recess or space of the sample zone.” As shown in Fig. 1, the instrument of Yokoyama et al. has a laminated structure composed of a hydrophilic absorbent disposed between two water resistant substrates. Openings in the substrates expose the absorbent located at the inner surface of the substrates. In other words, the absorbent is disposed above or below the openings of the two substrates, but is not retained inside the openings of a single substrate. Consequently, the Yokoyama et al. reference does not teach an absorbent retained inside the recess or space of the sample zone as set forth in independent Claim 1. Claims 2-6, 9-16, 22 and 23 all depend from independent Claim 1. Accordingly, Claims 1-6, 9-16, 22 and 23 are not anticipated by the Yokoyama et al. reference.

35 USC §103***Yokoyama et al. (Claim 7)***

Claim 7 is rejected under 35 USC §103(a) as being unpatentable over Yokoyama et al. for the reasons set forth in paragraph 17 of the office action. Applicants respectfully traverse the rejection as the proposed modification of the Yokohama et al. device would change the principle of operation of the device.

The Yokoyama et al. reference describes an instrument for collecting and sampling oral secretions, which simultaneously sterilizes oral bacteria and suppresses the decomposition of D-glucose in the oral secretions liquid. As shown in Fig. 1, the instrument can be inserted into the oral cavity to collect a saliva sample. The saliva sample passes through the openings in the substrates to the absorbent located between the substrates. The absorbent inside the laminated instrument comprises an absorption portion and a liquid holding portion, continuous with the absorption portion. Movement of oral secretions liquid from the absorption portion to the liquid holding portion provides a separation function removing impurities from the sample. The introduction of 20 and 200 sample zones, where the composition is retained inside the recess or space of each sample zone, would disrupt the flow path through the absorbent, which is responsible for filtration, sterilization, quantitation and recovery of the liquid sample. Moreover, the ability to collect 20 to 100 saliva samples by inserting the modified instrument into the oral cavity would not be predictable. Consequently, the device of claim 7 is not an obvious modification of the Yokoyama et al. reference.

Yokoyama et al. in view of Charlton et al. (Claim 8)

Claim 8 is rejected under 35 USC §103(a) as being unpatentable over Yokoyama et al. in view of Charlton et al. (US 5,989,921) for the reasons set forth in paragraph 19 of the Office Action. Applicants respectfully traverse the rejection as the Charlton et al. reference fails to correct the deficiencies of the Yokoyama et al. reference.

The Charlton reference describes a multi-layer test cell, where a permeable material is housed within an outer casing. The permeable material is capable of transporting an aqueous

solution by capillary action, wicking or simple wetting, along a flow path. Two circular openings in the casing, the control site and the test site, are disposed along the flow path. As in the Yokoyama et al reference, the permeable material provides a filtering means, among other functions. Accordingly, modification of either the Yokohama et al. or the Charlton et al device so that it comprises a plurality of sample zones, where the composition is retained inside the recess or space of each sample zone, would interrupt transport and filtration of the sample along a continuous flow path. Accordingly, the device of claim 8 is not obvious over Yokoyama et al. in view of Charlton et al. as neither reference teaches or suggests a plurality of sample zones, where the composition is retained inside the recess or space of each sample zone.

Yokoyama et al. in view of Fukunishi et al. (Claim 17)

Claim 17, which depends from claim 1, is rejected under 35 USC §103(a) as being unpatentable over Yokoyama et al. in view of Fukunishi et al. (US 6,084,005) for the reasons set forth in paragraphs 21 and 22 of the office action. Applicants respectfully traverse the rejection as the Fukunishi et al. reference fails to overcome the insufficiencies of the Yokoyama et al. reference. Yokohama et al. teaches the use of cetylpyridinium chloride as a bactericidal ingredient, whereas Fukunishi et al. teaches the use cetylpyridinium hydrochloride as microbiocide in an antimicrobial caries-detecting composition. However, the Fukunishi et al. reference does not overcome the deficiencies of the Yokohama et al. with respect to the claimed features of independent Claim 1. In other words, Fukunishi et al. are silent regarding a device “where a composition comprising i) one or more than one absorbent, and ii) one or more than one stabilizer in a solid state”... “is retained within the support inside the recess or space of the sample zone.” Accordingly, the device of claim 17 is not obvious over Yokoyama et al. in view of Fukunishi et al.

Yokoyama et al. in view of Zhang-Keck and Stallcup (Claims 18-21)

Claims 18-21 are rejected under 35 USC §103(a) as being unpatentable over Yokoyama et al. in view of Zhang-Keck and Stallcup. (Journal of Biological Chemistry, vol. 263, No. 7, pp3514) for the reasons set forth in paragraphs 24 and 25 of the Office Action. Applicants

respectfully traverse the rejection.

The Yokohama et al. reference is silent regarding the limitations of claims 18-21. The Zhang-Keck reference describes solutions containing Tris buffer and EDTA for transcription reactions, column chromatography, hybridization and T1 ribonuclease reactions. The Zhang-Keck reference also includes BSA in a transcription buffer. Moreover, the Zhang-Keck reference describes the use vanadyl ribonucleoside complex as a ribonuclease inhibitor in the nuclear transcription reactions. Claims 18-20 depend from Claim 1 and Claim 21 depends from Claim 11. There is no suggestion in the Zhang-Keck reference that any of these components are suitable for use as a stabilizer (Claims 18-20) or additive (Claim 21) in a solid state, as recited in Claim 1 or 11. Moreover, the Zhang-Keck and Stallcup. reference does not overcome the previously described deficiencies of the Yokohama et al. reference with respect to the claimed features set forth in independent claim 1. Accordingly, devices in accordance with claims 18-21, which ultimately depend from Claim 1, are not obvious over Yokoyama et al. in view of Zhang-Keck and Stallcup.

Examiner's articulated reasoning to support the legal conclusion of obviousness for Claims 7, 8, and 17-21 is clearly insufficient to support a case of *prima facie* obviousness. In view of the foregoing deficiencies, Applicants respectfully request withdrawal of the rejection of Claims 7, 8, and 17-21 as being unpatentable under 35 §103(a).

Conclusion

Although Paragraph 26 of the Office Actions states that Claims 1-24 are rejected, Applicants note that the Office Action has not provided any reason for rejecting Claims 15 and 24. Moreover, Applicants respectfully submit that the prior art cited, does not teach one of skill in the art all of the features set forth in Claim 1. Given that dependent Claims 2-24 all ultimately depend from independent Claim 1, they are likewise distinguishable from the cited references. The absence of additional patentability arguments should not be construed as either a disclaimer of such arguments or that such arguments are not believed to be meritorious.

Applicants believe that all pending claims are in condition for allowance and such action is earnestly requested. If the present amendments and remarks do not place the Application in condition for allowance, the Examiner is encouraged to contact the undersigned directly if there are any issues that can be resolved by telephone with the Applicants' representative.

No fee is believed due with the Response. However, the Commissioner is hereby authorized to charge payment of any fees associated with this communication to Deposit Account No. 19-2090.

Respectfully submitted,

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Date: July 21, 2009

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